

### **REMARKS**

Applicant wishes to thank the Examiner for the consideration given this case to date. Applicant has now had an opportunity to carefully consider the Examiner's action, and respectfully submits that the application, as amended, is now in condition for allowance. Currently, claims 1-3 and 5-8 and 10 are pending.

### **THE EXAMINER'S ACTION**

In the Office Action dated July 15, 2003, the Examiner:

rejected claims 1-3 and 5-10 under the judicially created doctrine of obviousness-type double patenting over Sandberg, U.S. Patent No. 6,069,129 (the "'129 patent") in view of Kligman, U.S. Patent No. 4,877,805 ("Kligman") and Sheffield, EP Appln. No. 0-339-0905 ("Sheffield");

rejected claims 8-10 under 35 U.S.C. § 112, second paragraph, as being indefinite;

rejected claims 1-3 and 5-10 under 35 U.S.C. § 103(a) as being obvious in light of Sandberg, WO 99/95941 in view of Kligman and Sheffield; and

rejected claims 1-3 and 5-10 under 35 U.S.C. § 103(a) as being obvious in light of the '129 patent in view of Kligman and Sheffield.

### **DOUBLE PATENTING**

The Office has rejected claims 1-3 and 5-10 under the judicially created doctrine of obviousness-type double patenting over the '129 patent in view of Kligman and Sheffield. The Office asserts that Kligman teaches the use of retinoids in therapeutic cosmetic compositions to improve damaged human skin and Sheffield teaches the use of retinoids as an effective wound healing agent in compositions comprising at least one peptide and a retinoid. The Office has taken the position that it would have been prima facie obvious for one of ordinary skill in the art to make the cosmetic and/or dermatological composition and methods of the '129 patent and modify the claims to include retinoids as taught by Kligman and Sheffield.

Initially, the '129 patent fails to suggest or teach any retinoids. Furthermore, the claims of the '129 patent do not include SEQ ID 45-54. For example, claim 1 of the '129 patent calls for a composition comprising a peptide selected from the group consisting of SEQ ID 17, SEQ ID 18, SEQ ID 19, and SEQ ID 23. Moreover, Kligman fails to suggest or teach any peptides. Sheffield also fails to teach the use of the claimed peptides. In contrast, Sheffield teaches the use of retinoids and at least one growth factor for increasing the rate of wound healing (pg. 1, lns. 1-2). Sheffield teaches that the growth factors must have mitogenic and angiogenic activity (pg. 2, lns. 9-11). Sheffield further identifies only epidermal growth factor, acidic and basic fibroblast growth factor, platelet derived growth factor, transforming growth factor, insulin-like growth factor, and nerve growth factor as displaying such activity. (pg. 2, lns. 19-23; pg. 3, lns. 28-33). These growth factors are all large polypeptides of more than 50 amino acids (pg. 2, lns. 26-27). There is no teaching or suggestion in Sheffield that the growth factors of Sheffield increase the endogenous production of elastin, or that the growth factors display such activity. Moreover, there is no suggestion or motivation to substitute the wound healing agents of Sheffield with other peptides, namely SEQ ID 17 and 45-54.

As amended, the instant claims call for a retinoid or skin enhancing agent, and a peptide selected from the group of SEQ ID 17 and 45-54. None of the references teach or suggest the sequences in the instant application, namely SEQ ID 45-54. The references also do not contain any motivation or teaching to modify SEQ ID 17. Moreover, there is no motivation or teaching to modify SEQ ID 17 to arrive at SEQ ID 45-54. Furthermore, none of the references teach or suggest the use of these specific peptide sequences in combination with retinoids. As noted above, the '129 patent fails to teach retinoids and Kligman fails to teach any peptide. Furthermore, Sheffield is directed specifically to wound healing and teaches only wound healing growth factors. Sheffield states that only the growth factor peptides identified in the reference are required for wound healing (pg. 2, lns. 22-23; pg. 3, lns. 28-30). There is no suggestion in Sheffield to substitute any other peptide in place of the growth factor peptides.

In fact, Sheffield teaches that for a wound healing agent, a peptide structure used in conjunction with a retinoid must display both mitogenic and angiogenic activity. Sheffield

identifies only a particular set of growth factors which display such activity, which all comprise a large number of amino acids. Only based on the teachings of the instant specification would one of ordinary skill in the art arrive at SEQ ID 45-54. Moreover, only in hindsight, based upon the teachings of the instant specification would one of ordinary skill in the art be motivated to combine the particular sequences, specifically SEQ ID 17 and 45-54 with a retinoid or skin enhancing agent to arrive at the Applicant's claims. Hindsight is an improper standard for obviousness and without any teachings or suggestions to combine the references, such a rejection cannot be supported, and the Applicant respectfully submits that the rejection has been overcome.

#### **REJECTIONS UNDER 35 U.S.C. § 112**

The Office as rejected claims 8-10 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Office asserts that the scope of the claims are uncertain since the claims recite a trademark, namely Retin A, to identify a material. The presence of a trademark or tradename in a claim is not *per se* improper under 35 U.S.C. § 112. MPEP § 2173.05(u). However, claim 8 has been amended to recite "tretinoin." In light of the amendment, Applicant respectfully submits that the rejection has been overcome.

#### **REJECTIONS UNDER 35 U.S.C. § 103**

The Office has rejected claims 1-3 and 5-10 under 35 U.S.C. § 103(a) as being obvious in light of Sandberg, WO99/45941, in view of Kligman and Sheffield.

As amended, the claims call for a composition of a retinoid and a peptide of SEQ ID 17 and 45-54. Sandberg does not suggest or teach the use of a retinoid. Kligman does not suggest or teach the use of a peptide. Sheffield is directed to wound healing and identifies a particular set of growth factors with such activity, but fails to suggest that these particular growth factors may be substituted with any other peptides, specifically SEQ ID 17 and 45-54 to increase endogenous elastin production. None of the references teach or suggest the sequences of the instant application, namely SEQ ID 45-54. The references also do not contain any motivation or teaching to modify SEQ ID 17 and in addition, there is no motivation or teaching to modify SEQ

ID 17 in the specific manner of Applicant to arrive at SEQ ID 45-54. Furthermore, none of the references teach or suggest the use of the specific peptide sequences of SEQ ID 17 and 45-54 in combination with retinoids. In fact, Sheffield teaches that a particular set of growth factors comprising more than 50 amino acids in length may be combined with retinoids for wound healing. However, the growth factors of Sheffield are not the elastin-derived peptide fragment sequences found in Applicant's claims. Only in hindsight based upon the teachings of the instant specification would one of ordinary skill in the art identify the particular sequences, specifically SEQ ID 17 and 45-54 in combination with a retinoid. Hindsight is an improper standard for obviousness and without any teachings or suggestions in the references, the Applicant respectfully submits that the rejection has been overcome.

The Office has rejected claims 1-3 and 5-10 under 35 U.S.C. § 103(a) as being obvious in light of the '129 patent in view of Kligman and Sheffield.

As amended, the claims call for a composition of a retinoid and a peptide of SEQ ID 17 and 45-54. Kligman fails to teach the use of any peptide. The '129 patent does not teach or suggest the use of retinoids. Sheffield, directed to wound healing, contains no suggestion to substitute the growth factors, specifically identified as wound healing growth factors, with any other peptide. Neither Kligman or Sheffield teach or suggest the sequences in the instant application. The references also do not contain any motivation nor teaching to modify SEQ ID 17, nor to modify SEQ ID 17 in the specific manner of Applicant to arrive at SEQ ID 45-54. Furthermore, none of the references teach or suggest the use of these specific peptide sequences in combination with retinoids. Only in hindsight, based upon the teachings of the instant specification, would one of ordinary skill in the art identify the particular sequences, specifically SEQ ID 17 and 45-54 in combination with a retinoid. Hindsight is an improper standard for obviousness and without any teachings or suggestions in the references, the Applicant respectfully submits that the rejection has been overcome.

### **CLAIM OBJECTIONS**

The Office has objected to claim 9 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of the previous claim. In light of the

amendment to claim 8, Applicant has canceled claim 9 and as such, the objection should be withdrawn.

**CONCLUSION**

Applicant appreciates the Examiner's attention to this matter. Please charge any additional fees or credit any overpayments to Deposit Account 02-2051 referencing Attorney Docket No. 25812-74.

Respectfully submitted,

BENESCH, FRIEDLANDER  
COPLAN & ARONOFF LLP

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W. Scott Harders  
Reg. No. 42,629  
2300 BP Tower  
200 Public Square  
Cleveland, OH 44114-2378  
(216) 363-4443